

## **DETAILED ACTION**

### ***Response to Amendment***

The Information Disclosure Statement (IDS) filed 14 August 2009 has been entered. Applicant's amendment of the claims filed 11 September 2009 has been entered.

### ***Election/Restrictions***

Independent claim 125 is directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 87 and 89, directed to the process of using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, the restriction requirement between Groups I and II as set forth in the Requirement for Restriction Election mailed 8 March 2005 is hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C.

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121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1-76, 79, 88, 90-124, 130-136 and 139 are cancelled. Claims 140-148 have been added. Claims 77, 78, 80-87, 89, 125-129, 137, 138 and 140-148 are pending.

### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in telephone interviews with attorney Angela M. Domitrovich on 30 December 2009 and 21 January 2010.

#### Please amend the claims as follows:

84. A method of producing a fusion protein of Claim 125, comprising:
  - a) transfecting or transforming an isolated host cell with an expression vector comprising a nucleic acid encoding the fusion protein of Claim 125;
  - b) culturing the host cell under conditions effective to express said fusion protein; and
  - c) harvesting the fusion protein expressed by the host cell.
87. A method of treating a condition of a deficient hematocrit, comprising administering an effective amount of the fusion protein of Claim 125, wherein administration of the fusion protein increases the hematocrit of the patient.
125. A fusion protein comprising a full-length human erythropoietin protein joined without an intervening peptide linker to a human immunoglobulin (Ig) domain that does not contain a variable region wherein the Ig domain is selected from the group consisting of full-length IgG-Fc, IgG-C<sub>H</sub> and IgG-C<sub>L</sub>, wherein the fusion

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protein consists of the natural human erythropoietin amino acid sequence and the natural human immunoglobulin domain amino acid sequence at the junction of the fusion protein.

126. A fusion protein comprising a full-length human erythropoietin protein joined without an intervening peptide linker to a human immunoglobulin (Ig) domain that does not contain a variable region wherein the Ig domain is selected from the group consisting of full-length IgG-Fc, IgG-C<sub>H</sub> and IgG-C<sub>L</sub>, wherein the fusion protein consists of the natural human erythropoietin amino acid sequence and the natural human immunoglobulin domain amino acid sequence at the junction of the fusion protein, and wherein the fusion protein has an EC<sub>50</sub> of less than about 10 ng/ml in an EPO-dependent *in vitro* bioassay using a human UT7/epo cell line that proliferates in response to EPO.
137. A fusion protein comprising a full-length human erythropoietin protein joined without an intervening peptide linked to a human immunoglobulin (Ig) domain that does not contain a variable region wherein the Ig domain is selected from the group consisting of full-length IgG-Fc, IgG-C<sub>H</sub> and IgG-C<sub>L</sub>, wherein the fusion protein consists of the natural human erythropoietin amino acid sequence and the natural human immunoglobulin domain amino acid sequence at the junction of the fusion protein, and wherein the fusion protein has an EC<sub>50</sub> of less than about 1000 ng/ml in an EPO-dependent *in vitro* bioassay using a human UT7/epo cell line that proliferates in response to EPO.

Please cancel claims 89, 127, 138 and 140-148.

The following is an examiner's statement of reasons for allowance: the amendment to the claims was made to clarify the claimed invention. Applicant's response and the claim amendment submitted on 11 September 2009 overcame all remaining grounds of rejections and objections. Claims 89, 127, 138 and 140-148 are cancelled without prejudice to Applicant's intention to pursue the subject matter therein in continuing applications in the telephonic responses with the attorney on 30 December 2009 and 21 January 2010.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.  
January 11, 2010

/Gary B. Nickol /  
Supervisory Patent Examiner, Art Unit 1646